求人情報

スタッフレベル

ポジション名	Clinical Research Specialist
この求人情報の取扱い会社	マイケル・ペイジ・インターナショナル・ジャパン株式会社/Michael Page International Japan K.K.
企業名	会社名非公開
掲載開始・更新	2024-05-02 / 2024-05-02
職　種	メディカル/医薬/バイオ/素材/食品 - 臨床開発系
業　種	製薬メーカー
勤務地	アジア 日本 東京都
仕事内容	* As a member of trial team, participate in site monitoring activities throughout the course of a trial, to safeguard the protection of the trial subject, reliability of the trial results, compliance with study protocol, ICH-GCP and applicable regulations and ensure inspection readiness at all times. Description * Attendance of training for internal CRA appointments * Meetings and appropriate communication with internal and external stakeholders as required for the conduct of the study * Research into the selection of medical institutions * Set-up of clinical sites * Explanation of procedures, including the study protocol, to site personnel (physicians, CRCs, secretariat, laboratory technicians, etc.) * Providing necessary training to medical institution personnel * Preparation and submission of IRB/EC documents required by the implementing medical institution * Consultation and conclusion of contracts with implementing medical institutions * Delivery and confirmation of medicines (including investigational medicines) and materials delivered to the site * Monitoring and facilitation of case enrollment at investigational sites * Conducting SDV and SDR at set frequencies * Appropriate reporting and review of adverse events occurring in study participants * Dissemination of necessary safety information to sites * Ensuring that medicines (including investigational medicinal products) and materials delivered to the site are appropriately managed (and collected if necessary) * Confirmation that site personnel have received the necessary training and understand the regulations and procedures required to conduct the study * Ensuring that the data obtained from the study are entered appropriately in the case report form and that this is confirmed * Appropriate reporting of information obtained from monitoring activities (preparation of monitoring reports and entry into the required tracking systems) * Achieving milestones at your institution, both internally and in collaboration with your institution * Responding to regulatory investigations and internal audits of the implementing medical institution Profile * Ability to carry out monitoring in accordance with GCP * Experience as a CRA in several international trials * Experience in charge of facilities at a university hospital or a core hospital * English proficiency score (TOEIC 730 or above, EIKEN level 2, etc.) * Able to communicate directly in English with overseas vendors, etc. (with no difficulty in reading and

	writing) Job Offer * Contribute to the effective development of drugs within the speciality care area * Work in global clinical trials as part of Japan and East Asian Hub * Promotion opportunities in Clinical Trial Management area Page Group Japan is acting as an Employment Agency in relation to this vacancy.
企業について(社風など)	* World leading multinational pharmaceutical company with broad development pipeline including new drugs, biosimilars and generics.
英語能力	ビジネス会話 (TOEIC 735-860)
日本語能力	流暢（日本語能力試験1級又はN1)
年　収	日本・円 600万円 ～ 800万円